REMARKS

Claims 1-24 were pending in the present application. Claims 1-10 have been canceled, Claims 11-24 have been amended, and Claims 25 and 26 have been added, leaving Claims 11-26 for consideration upon entry of the present Amendment. Applicant acknowledges that the Examiner has renumbered claims 2-15 as submitted in a Preliminary Amendment dated June 21, 2001 to read as numbered claims 11-24. In light of the Examiner's renumbering, Applicant has amended Claims 12-24 to provide proper claim dependency. Support for the claim amendments is found in the specification and claims as originally filed. The additional claims have been made for the purpose of further claiming the invention, rather than to overcome any rejections related to patentability. Support for the amendment made to Claim 25 is found at Page 4, lines 92-94 of the Specification as originally filed and in Claims 6 and 9 as filed in the Preliminary Amendment. Support for the amendment made to Claim 26 is found in Claim 6 as filed in the Preliminary Amendment. Applicant submits that, although the phrase "highairways diseases" appears in Claim 6, "upper respiratory disorders" as used in Claim 26 is equivalent to "highairways diseases" and that the amendment is made only to clarify the term "highairway." Additionally, a Substitute Specification has been included in this Amendment. No new matter has been introduced by the amendments made to either the specification or to the claims as antecedent support is set forth in the original specification and in the original claims. Reconsideration and allowance of the claims is respectfully requested in view of the above amendments and the following remarks.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 11-24 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the applications was filed, had possession of the claimed invention. In particular, the Examiner states that, while the specification is enabling for the use of alpha-hydroxypropionic acid to treat sinusitis, it does not reasonably provide enablement for any and all respiratory diseases. Applicant respectfully traverses this rejection. Applicant submits that the Specification provides

sufficient support for the claim language. One or ordinary skill in the art would be able to appreciate the remedial potentials of the composition applied according to the specified disclosure. Applicant respectfully requests reconsideration and withdrawal of this rejection.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 11-24 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, Claim 11 is rejected as no recipient is recited, and the wording of the claim allegedly renders the method unclear. Applicant has amended Claim 11 as suggested by the Examiner.

Claim 15 is rejected as the word "includes" renders it unclear as to what other diseases are intended to be claimed. Applicant has amended Claim 15 to clarify that "includes" refers to respiratory diseases such as, but not necessarily limited to, sinusitis and high airway diseases.

Claims 15 and 16 are rejected as it is not clear what "highairway" disease means. Applicant has amended the term "highairway" as used in Claims 15 and 16 to read "high airway." Applicant respectfully submits that one of ordinary skill in the art would understand this phrase to mean the upper airway system.

Claim 19 is rejected as it is not clear what is meant by "clearing agent of nasal cavities." Applicant has amended Claim 19 to state in part: "wherein the medicine is used as a clearing agent of nasal cavities and cheekbones." Support for this amendment is found at Page 3, lines 46-55 of the Specification as originally filed. Applicant respectfully submits that one of ordinary skill in the art would decipher the meaning of this claim as pertaining to the removal of undesired or disease-causing agents from the nasal cavities and the cheekbones. Because one of ordinary skill in the art would appreciate the meaning of the claim language, Applicant respectfully requests reconsideration and withdrawal of the rejection.

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 11-24 stand rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over Japanese Patent No. JP 63-170323A to Kobu et al. ("Kobu"). Kobu allegedly discloses that alpha-hydroxypropionic acid is useful in the treatment of respiratory disease. The Examiner states that the instant claims differ over the reference in cited amounts and specific solvents. However, in the absence of a showing of unexpected results commensurate in scope with the claims in Declaration form, once a method of using a compound is known it would be obvious to one of ordinary skill in the art to determine the optimum amount and solvent. Applicant respectfully traverses this rejection.

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing a prima facie case of obviousness. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Establishing a prima facie case of obviousness requires that all elements of the invention be disclosed in the prior art. *In re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A 1970).

Kobu teaches an active principle of the pericarp extract of citrus fruits, comprising pectins and citric acid. The active principle is a beta-hydroxy-tri-carboxylic acid, which may be used in the treatment of bronchia asthma, and some allergic rhinites and dermatitis. The water soluble extract thereof may be freeze-died and turned into powder for nasal use. Unlike Kobu, however, Applicant claims a composition comprising in part alpha-hydroxypropionic acid. Applicant submits that the alpha-hydroxypropionic acid claimed in Claims 12-24 is different from the active principle taught in Kobu. Unlike the active principle taught in Kobu, which is a tricarboxylic acid, alpha-hydroxypropionic acid is a mono carboxylic acid, which has very different chemical properties.

Aside from the basic differences in the chemical composition of the two compounds, the methods used to isolate the two components are very different from each other. Alpha-hydroxypropionic acid is typically obtained by fermenting glucose, maltose, or saccharose solutions with microorganisms, such as, *Bacillus acidi lactici* or *Bacterium delbrucki*. The solutions include nitrogenized compounds, peptones, ammonium salts, blood albumin, and phosphates. Unlike the method of forming alpha-hydroxypropionic acid, the method used to

obtain the active component taught in Kobu is based on extracting the component from the pericarp of *Citrus Markov* with a hydro-alcoholic solution steeped for several days.

As the active compound claimed by Applicant is chemically different from the active component taught by Kobu, and because the methods of forming the two compounds are very different, Applicant submits that the two compounds are very different. Accordingly, Applicant submits that Kobu does not teach the alph-hydroxopropionic acid claimed by Applicant. Therefore, Applicant respectfully requests reconsideration and withdrawal of the rejection.

New Claims

Claims 25 and 26 have been added to further claim the invention. Applicant respectfully submits that these claims are allowable.

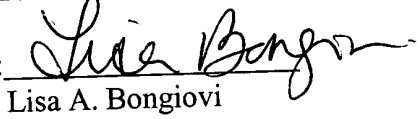
In addition, attached hereto is a marked-up version of the changes made to the application. The attached page is captioned "**Version with Markings to Show Changes Made**."

In view of the foregoing, it is respectfully submitted that the instant application is in condition for allowance. Accordingly, it is respectfully requested that this application be allowed and a Notice of Allowance issued. If the Examiner believes that a telephone conference with Applicant's attorneys would be advantageous to the disposition of this case, the Examiner is cordially requested to telephone the undersigned.

In the event the Commissioner of Patents and Trademarks deems additional fees to be due in connection with this application, Applicant's attorney hereby authorizes that such fee be charged to Deposit Account No. **06-1130.**

Respectfully submitted,

CANTOR COLBURN LLP

By: 

Lisa A. Bongiovi
Registration No. 48,933
CANTOR COLBURN LLP
55 Griffin Road South
Bloomfield, CT 06002
Telephone (860) 286-2929
Facsimile (860) 286-0115
Customer No. 23413

September 23, 2002

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please amend Claims 11-24 in "marked up" format, as follows:

Claim 11. (Amended/Marked-up) A method of treating an upper respiratory disease in a human or an animal in need thereof, the method comprising:

administering to a nasal passageway of the human or the animal a composition~~using alpha-hydroxypropionic acid as a medicine for treating a respiratory disease,~~ comprising ~~adding the~~ alpha-hydroxypropionic acid and~~to~~ a pharmaceutically acceptable vehicle, wherein the alpha-hydroxypropionic acid in a concentration of 0.2-10 vol.% based on the volume of the acceptable pharmaceutical vehicle.

Claim 12. (Amended/Marked-up) The method as claimed in claim 11~~2~~, wherein the pharmaceutically acceptable vehicle is selected from the group consisting of 1,2,3-propanotriol, 1,2-propanodiol, and serum.

Claim 13. (Amended/Marked-up) The method as claimed in claim11~~-2~~, wherein the alpha-hydroxypropionic to be added is 85 vol.% aqueous solution.

Claim 14. (Amended/Marked-up) The method as claimed in claim 13~~4~~, wherein 0.2ml-4.0 ml of the aqueous alpha-hydroxypropionic solution is added to a mixture solution of 70ml of 1,2,3-propanotriol and 30ml of 1,2-propanodiol.

Claim 15. (Amended/Marked-up) The method as claimed in claim 11~~2~~, wherein the upper respiratory disease includes sinusitis or~~and~~ high airways diseases.

Claim 16. (Amended/Marked-up) The method as claimed in claim 11~~2~~, wherein the medicine is used for treating human and veterinarian high airway diseases.

Claim 17. (Amended/Marked-up) The method as claimed in claim 11~~2~~, wherein the medicine is used as a nasal releaser.

Claim 18. (Amended/Marked-up) The method as claimed in claim 11~~2~~, wherein the medicine is used for treating rhinitis.

Claim 19. (Amended/Marked-up) The method as claimed in claim 11~~2~~, wherein the medicine is used as a clearing agent of nasal cavities and cheekbones.

Claim 20. (Amended/Marked-up) The method as claimed in claim 12~~3~~, wherein the pharmaceutically acceptable vehicle is 1,2,3-propanotriol.

Claim 21. (Amended/Marked-up) The method as claimed in claim 12~~3~~, wherein the pharmaceutically acceptable vehicle is serum.

Claim 22. (Amended/Marked-up) The method as claimed in claim 12~~3~~, wherein the pharmaceutically acceptable vehicle is 1,2-propanodiol.

Claim 23. (Amended/Marked-up) The method as claimed in claim 11~~2~~, further comprising formulating a mixture of the alpha-hydroxypropionic acid and the pharmaceutically acceptable vehicle into a pharmaceutically acceptable form which is adapted to be administered to human and animal.

Claim 24. (Amended/Marked-up) The method as claimed in claim 23~~14~~, wherein the pharmaceutically acceptable form includes a solution for intake in drops, spray, and a fine powder.

SUBSTITUTE SPECIFICATION WITH MARKED CHANGES

A COMPOSITION FOR THE TREATMENT OF RESPIRATORY DISORDERS AND A METHOD FOR ITS USE~~"NEW UTILIZATION OF ALPHA HIDROXI PROPIONIC ACID IN MEDICINE"~~

TECHNICAL FIELD

The present invention ~~is~~ relate~~sive~~ to a composition for the treatment of sinusitis and rhinitis and other respiratory disorders. The composition comprises ~~compound made of~~ alpha-hy~~i~~droxy~~i~~-propionic (or 2-hy~~i~~droxyl~~i~~-propionic), popularly known as Lactic Acid, linked to an appropriate vehicle so that it may be used via the nasal airways.~~(compound I), combined with 1,2,3 propanotriol pure (glicerin), or to the 1,2-propanodiol pure or serum, or to a balanced mixture of them or any other acceptable pharmaceutic vehicle, (compound II) to the attaining procedures of such a compound or to its utilization in Medicine.~~

BACKGROUND OF THE INVENTION

Presently, there is no efficient medication for sinusitis and rhinitis treatment. Rather, treatment for these disorders lies primarily in the use of antibiotics. Aside from being economically costly, current antibiotic treatment poses a substantial risk to the public health as overuse results in antibiotic resistance. Antibiotic treatment also has limited applicability in the treatment of respiratory disorders, such as sinusitis. As known, sinusitis is an inflammation of the layer of the tissue that internally covers the cheekbones through little holes (sinuses) that communicate with the nasal cavity directly linked to the external environment. For a biologically active substance to carry out its duty, it is desirable to be positioned at the action location. The active principles are taken into the body through medicines. Therefore it is desirable for them to be released in the location where the infectious agents are. In fact, the antibiotic is a medicine for internal use and that is why it is not efficient in the sinusitis treatment, taking into consideration that its release does not occur at the infection spot. Rather, antibiotic treatment typically

begins once the patient suffering from the respiratory disorder is in acute crisis. During the crisis stage, germs located in external areas of the organism or in close contact with the external environment, i.e., in the nasal cavity or in the sinuses of the cheekbones, are not reached. Accordingly, the use of antibiotics is inefficient in the treatment of respiratory disorders such as sinusitis and rhinitis.

SUMMARY OF THE INVENTION

The present composition aims at solving the above problems, being especially produced for application through the nasal airways. The composition comprises an alpha-hydroxypropionic acid or an acceptable pharmaceutical dilution thereof, linked to an appropriate vehicle applied through the nasal cavities of patients in need thereof.

DETAILED DESCRIPTION OF THE INVENTION

The composition of the present disclosure comprises~~invention has got~~ an active compound consisting~~ed~~ of ~~the~~ alpha-hy~~i~~droxy~~i~~-propionic acid, or an acceptable pharmaceutical dilution thereof, linked to an appropriate vehicle for application through the nasal cavities of a patient in need thereof. The active compound utilized in the composition comes in an aqueous solution made of 15% water in 85% of acid. The vehicle may be a serum or any other pharmaceutical capable of carrying the active compound through the nasal cavities. The ideal composition of the vehicle is associated with is 70% of 1,2,3-propanotriol (glycerin) and 30% of 1,2-propanodiol (propilenoglycol). It has been detected that acceptable dilutions of the active compound in the vehicle are 0.2 ml to 4.0 ml of the alpha-hydroxypropionic acid for each 100 ml of the vehicle. ~~(compound I), or to an acceptable pharmaceutic salt of the latter, or of an acceptable pharmaceutic solvato of the latter, or of an acceptable pharmaceutic catalyser of the latter, characterized by the following dilution of:~~

~~0,2 to 0,9ml, or 1,1 to 2,0ml, or 2,1 to 3,0ml, or 3,1 to 4,0 ml, or 4,1 to 5,0ml, or 5,1 to 6,0ml, or 6,1 to 10ml of compound I in 100ml of compound II; and 0,3 to 0,8ml, or 0,4 to 0,7 ml, or 0,2 to 0,5ml, or 0,5 to 0,9 ml, or 1,1 to 1,5ml, or 1,5 to 2,0ml,~~

~~or 2,1 to 3,0ml, or 3,1 to 4,0ml, or 4,1 to 5,0 ml or 5,1 to 10,0 ml of the active principle of compound I in 100ml of compound II.~~

The suggested dosage is in an amount that will result in desired effects obtained during the application of the composition via the nasal airways, either in drops or in a spraying solution.~~Compound I, in one or more of the above mentioned items combined with compound II is characterized by being suit to the intake in drops, via the nasal airways, or as a spraying solution, a spray, a microfine powder for insufflation or an acceptable pharmaceutic salt or an acceptable pharmaceutic solvate for the medicine addressed to the treatment of the highairways disturbances.~~

~~There aren't in the medical and pharmaceutical literautes any statements about the active principle of compound I. On the other hand, there isn't an efficient medicine for the sinusitis treatment. What has been recorded in medical literature so far is the antibiotics massification which, besides its high cost, represents one of the biggest threats to the world public health, due to the development of resistant "cepas" (germs).~~

~~It's to be pointed out that the antibiotics massification leads only to the germs fight inside the organism or in its "doorway" when such disturbances are in acute crisis. During those crisis, the germs either in the nasal cavities or in the cheek bones located in external areas of the organism, in close contact with the external environment, aren't reached.~~

~~For a biologically active substance to carry out its duty, it's necessary to be positioned at the action location. The active principles are taken into the body through medicines. Therefore, it's necessary for them to be released in the location where the infectious agents are.~~

~~In fact, the antibiotic is a medicine for internal sue and that's why it isn't efficient in the sinusitis treatment, taking into consideration that its release doesn't occur at the infection spot. As known, the sinusitis is an inflammation of the layer of the tissue that internally covers the cheek bones through little holes which communicate with the nasal cavity directly linked to the external environment.~~

As the application of the composition~~compound I linked to compound II~~ occurs at the nostrils, such a compound will work directly on the germs located in the nasal cavities and cheeks.

The first application effect of the composition in the nasal cavities and ~~cheek bones~~cheekbones ~~of compound I linked to compound II~~ is ~~the~~ ~~"lisar"~~ ~~(~~dehydration~~ng)~~ of the germs that can be found there through its bactericide and bacteriostatic properties ~~that are in contact~~.

After that, the hydrating and moistening effects of the composition~~compound I linked to compound II,~~ cause the increase in the nasal mucosa elasticity and its clearance. The action motion of the alpha-hy~~i~~droxy~~i~~-propionic acid keeps a more ho~~e~~mogeneous cornea layer, decreasing the superficial cellular cohesion. The~~ese~~ alpha-hy~~i~~droxy~~i~~-propionic acid~~s~~ promote~~s~~ a subtle exfoliation, leaving the nasal mucosa smoother and more homogeneous.

The composition effects media changes in the areas to which it is exposed. That is, the composition~~As mediate effects, there are also the~~ modifie~~seations of~~ the medium pH, facilitating growth of~~the~~ "*Lactobacyllus acidophyllus*" and ~~*the*~~ "*Bifidobacteria*" bacteria~~growth~~. ~~The~~ Growth of *Bifidobacteria* has beneficial effects upon the host organism. For example, *Bifidobacteria* are known for displaying inhibiting effects, both in vitro and in vivo, upon many other pathogenic germs, ~~"in vitro" and "in vivo",~~ such as "*Candida albicans*", "*Shighellas*", "*Clostridium*", "*Bacillus cereus*", "*Staphylococcus aureus*", and "*Campylobacter j~~J~~ejuni*"~~, according to the researches of Aann and col. (1985), Tojo and col. (1987), Tomoda and col. (1988)~~.

It i's known~~, as well,~~ that ~~*the*~~ *B~~b~~ifidobacteria* in the large intestine synthesize beneficial vitamins that are absorbed by the organism.

Bifidobacteria are ~~still~~ known for producing thiamine, riboflavine and vitamins B6 and K. It's still proved that the *B~~b~~ifidobacteria* are able to ~~synthetize~~synthesize ~~the~~ complex B vitamins ~~(Mutai, 1978)~~.

It is believed that the *Bifidobacteria*, by competition, also remove from the large intestines putrefying bacteria which are responsible for the release of free radicals. Free radicals, which are absorbed by the host organism, tend to create harm to the host, such as early aging.

Similarly to the gastrointestinal tract, the respiratory system is open to the external environment in order to facilitate the host organism's breathing. In the cheek bones, the present medication changes the medium pH, promoting ~~the~~ mucosa

hydrationng which will speed up *Bifidobacteria* growth. The *Bifidobacteria*, by competition, leaves out the pathogenic bacteria found there, which are responsible for infection of the cheek-bones ~~infections~~.

~~Well, similarly to the gastrointestional tract, the repiratory system is open to the extenal environment in order to facilitate the organism breathing. In fact, the bifidobacteria and "Lactobacyllus acidophyllus" growth in the cheek bones, is possible due to the optimum pH, determined by the active principles of compound I linked to compound II.~~

~~Researches believe that the bifidobacteria, by competition, leave out the large intestines putrefying bacteria which are responsible for the free radicals release. The free radicals, being absorbed, will do the organism a lot of harm, such as early aging. (Metchnikoff, 1938 and Linnus Pauling, 1965).~~

~~Therefore, the "Lactobacyllus acidophyllus" and Bifidobacteria presences are beneficial to the cheek bones as well as to the intestines.~~ One of the *Bifidobacteria* effects as an effective pathogenic germ inhibitor is associated with the production of lactates and acetates in small portions in the mechanism of reaction in the chemical products resultant from the carbohydrates catabolism. Those elements and the pH inhibit the pathogenic bacteria growth. ~~(Hughes, D.B., Hoover, D.G., BIFIDOBACTERIA, THEIR POTENTIAL FOR USE IN AMERICAN PRODUCTS).~~

U~~The medicine u~~tilization of the composition ~~, represented by compound I linked to compound II~~ is considered ~~only~~ by the otorhinolaryngologist clinics as a salutary alternative to ~~the~~ rhinitis and sinusitis treatment.

Carriers of such diseases feel considerable relief from the very first time they take the composition as disclosed herein. Additionally,~~referred medicine.~~

t~~T~~he composition ~~The medicine, represented by compound I linked to compound II,~~ has shown advantages upon any other medicine, for it isn't reabsorbed for being a product of cellular rejects.

~~At present, the sinusitis is treated with last generation antibiotics, not always with the desired results for not reaching the infection focus, which is inaccessible, and its massification leads to one of the biggest threats to the world public health due to the resistant "cepas" (germs) appearance _ what would justify this request at once.~~

~~The alpha hidroxi propionic acid utilization (compound I), linked to the 1,2,3 propanotriol or to the 1,2 propanodiol (compound II in the sinusitis treatment, besides being a profitable alternative in the treatment of those diseases, will bring huge social and economic benefits to the country.~~

CLEAN VERSION OF SUBSTITUTE SPECIFICATION

A COMPOSITION FOR THE TREATMENT OF RESPIRATORY DISORDERS AND A METHOD FOR ITS USE

This is a 371 of PCT/BR99/00107 filed 12/07/95

RE 01/30/03

TECHNICAL FIELD

The present invention relates to a composition for the treatment of sinusitis and rhinitis and other respiratory disorders. The composition comprises alpha-hydroxypropionic (or 2-hydroxyl-propionic), popularly known as Lactic Acid, linked to an appropriate vehicle so that it may be used via the nasal airways.

BACKGROUND OF THE INVENTION

Presently, there is no efficient medication for sinusitis and rhinitis treatment. Rather, treatment for these disorders lies primarily in the use of antibiotics. Aside from being economically costly, current antibiotic treatment poses a substantial risk to the public health as overuse results in antibiotic resistance. Antibiotic treatment also has limited applicability in the treatment of respiratory disorders, such as sinusitis. As known, sinusitis is an inflammation of the layer of the tissue that internally covers the cheekbones through little holes (sinuses) that communicate with the nasal cavity directly linked to the external environment. For a biologically active substance to carry out its duty, it is desirable to be positioned at the action location. The active principles are taken into the body through medicines. Therefore it is desirable for them to be released in the location where the infectious agents are. In fact, the antibiotic is a medicine for internal use and that is why it is not efficient in the sinusitis treatment, taking into consideration that its release does not occur at the infection spot. Rather, antibiotic treatment typically begins once the patient suffering from the respiratory disorder is in acute crisis. During the crisis stage, germs located in external areas of the organism or in close contact with the external environment, i.e., in the nasal cavity or in the sinuses of the cheekbones, are not reached. Accordingly, the use of antibiotics is inefficient in the treatment of respiratory disorders such as sinusitis and rhinitis.

SUMMARY OF THE INVENTION

The present composition aims at solving the above problems, being especially produced for application through the nasal airways. The composition comprises an alpha-hydroxypropionic acid or an acceptable pharmaceutical dilution thereof, linked to an appropriate vehicle applied through the nasal cavities of patients in need thereof.

DETAILED DESCRIPTION OF THE INVENTION

The composition of the present disclosure comprises an active compound consisting of alpha-hydroxypropionic acid, or an acceptable pharmaceutical dilution thereof, linked to an appropriate vehicle for application through the nasal cavities of a patient in need thereof. The active compound utilized in the composition comes in an aqueous solution made of 15% water in 85% of acid. The vehicle may be a serum or any other pharmaceutical capable of carrying the active compound through the nasal cavities. The ideal composition of the vehicle is associated with is 70% of 1,2,3-propanotriol (glycerin) and 30% of 1,2-propanodiol (propilenoglycol). It has been detected that acceptable dilutions of the active compound in the vehicle are 0.2 ml to 4.0 ml of the alpha-hydroxypropionic acid for each 100 ml of the vehicle.

The suggested dosage is in an amount that will result in desired effects obtained during the application of the composition via the nasal airways, either in drops or in a spraying solution. As the application of the composition occurs at the nostrils, such a compound will work directly on the germs located in the nasal cavities and cheeks.

The first application effect of the composition in the nasal cavities and cheekbones is dehydration of the germs that can be found there through its bactericide and bacteriostatic properties. After that, the hydrating and moistening effects of the composition cause the increase in the nasal mucosa elasticity and its clearance. The action motion of the alpha-hydroxypropionic acid keeps a more homogeneous cornea layer, decreasing the superficial cellular cohesion. The alpha-hydroxypropionic acid promotes a subtle exfoliation, leaving the nasal mucosa smoother and more homogeneous.

The composition effects media changes in the areas to which it is exposed. That is, the composition modifies the medium pH, facilitating growth of *Lactobacyllus acidophyllus* and *Bifidobacteria* bacteria. Growth of *Bifidobacteria* has beneficial effects upon the host organism. For example, *Bifidobacteria* are known for displaying inhibiting effects, both in vitro and in vivo, upon many other pathogenic germs, such as *Candida albicans*, *Shighellas*, *Clostridium*, *Bacillus cereus*, *Staphylococcus aureus*, and *Campylobacter jejuni*.

It is known that *Bifidobacteria* in the large intestine synthesize beneficial vitamins that are absorbed by the organism. *Bifidobacteria* are known for producing thiamine, riboflavine and vitamins B6 and K. It's still proved that the *Bifidobacteria* are able to synthesize complex B vitamins. It is believed that the *Bifidobacteria*, by competition, also remove from the large intestines putrefying bacteria which are responsible for the release of free radicals. Free radicals, which are absorbed by the host organism, tend to create harm to the host, such as early aging.

Similarly to the gastrointestinal tract, the respiratory system is open to the external environment in order to facilitate the host organism's breathing. In the cheekbones, the present medication changes the medium pH, promoting mucosa hydration which will speed up *Bifidobacteria* growth. The *Bifidobacteria*, by competition, leaves out the pathogenic bacteria found there, which are responsible for infection of the cheekbones.

One of the *Bifidobacteria* effects as an effective pathogenic germ inhibitor is associated with the production of lactates and acetates in small portions in the mechanism of reaction in the chemical products resultant from the carbohydrates catabolism. Those elements and the pH inhibit the pathogenic bacteria growth.

Utilization of the composition is considered by the otorhinolaryngologist clinics as a salutary alternative to rhinitis and sinusitis treatment. Carriers of such diseases feel considerable relief from the very first time they take the composition as disclosed herein. Additionally, the composition has shown advantages upon any other medicine, for it isn't reabsorbed for being a product of cellular rejects.